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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/578,522 | 05/08/2006 | Steven M. Leventer | 18184001801US | 5139 |
| 23973 | 7590 | 09/04/2008 | EXAMINER | |
| DRINKER BIDDLE & REATH | | | HUGHES, ALICIA R | |
| ATTN: INTELLECTUAL PROPERTY GROUP | | | | |
| ONE LOGAN SQUARE | | | ART UNIT | PAPER NUMBER |
| 18TH AND CHERRY STREETS | | | | 1614 |
| PHILADELPHIA, PA 19103-6996 | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 09/04/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/578,522 | LEVENTER ET AL. |
| | Examiner | Art Unit |
| | ALICIA R. HUGHES | 1614 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 03 March 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.
 4a) Of the above claim(s) 10-15 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-9 and 16-21 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Status of the Claims

Claims 1-21 are pending currently. Claims 1-9 and 16-21 are pending and they are the subject of this Office Action. Claims 10-15 are withdrawn from consideration, are withdrawn from consideration because they are not directed to the elected species.

Applicants' arguments, filed on 03 March 2008, have been fully considered and are deemed to be persuasive regarding the previous rejections. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn.

Upon reconsideration of the pending claims, as presented, the following new rejections are applied. They constitute the complete set of rejections being applied to the instant application presently.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 and 16-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,864,251 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '251 patent claims a method of treating an individual afflicted with an inflammatory disorder mediated by LTB₄ comprising the administration of the compound of the present invention while the present application is drawn to a method of treating an individual afflicted with an inflammatory disorder generally. The methods articulated in claims 1-12 of the '251 patent overlap in scope with the methods articulated in claims 1-9 and 16-21 of the instant invention.

For example, the instant application claims a method of treating an inflammatory condition of epithelial tissue that is a gastrointestinal disorder while the '940 application contemplates only the treatment of an inflammatory condition that is mediated by LTB₄. Both are, however, directed to treating inflammatory conditions and it is known in the art that LTB4 is

chemotactic for leukocytes and plays an important role in the development of gastrointestinal ulcers by contributing to the inflammatory process. See Fiorucci, Stefano, "Dual Inhibitors of Cyclooxygenase and 5-lipoxygenase. A New Avenue in Anti-Inflammatory Therapy?" *Biochemical Pharmacology*, Vol. 62, pages 1433-1438 (2001)(Abstract).

Furthermore, although the conflicting claims are not identical, they are not patentably distinct from each other because the prior art administering same compounds, in overlapping dosage amounts, inherently possessing therapeutic effect for the same ultimate purpose disclosed by the applicant anticipates the claimed invention even absence explicit recitation of underlying mechanism. Thus, it would have been obvious to a person of ordinary skill in the art at the time of invention to reduce inflammation by administering tofiospam.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ito, Chihiro, et al., "Pharmacological Studies of Tofiospam," *Res. Lab Pharmacol.*, Mochida Pharm. Co., Ltd., Tokyo, Japan (1981).

The teachings of Ito et al, as outlined in this Office's Action of 31 October 2007 are incorporated herein by reference in their entirety. Applicant argues that there is nothing in Ito et al that relates to the observed increase in pain threshold to any effect involving inflammation and

further, there is nothing in Ito et al that teaches or suggests the use of tofiospam for the treatment of an inflammatory disorder of the epithelium and no dose information is given by Ito et al either and finally, the present invention is distinguishable over the prior art in that the prior art does not meet the terminology “substantially free of the corresponding (S)-enantiomers” as defined by Applicants’ specification (Applicants’ Remarks of 03 March 2003 at Pages 4 and 5).

Ito, et al teach the pharmacological effects of tofiospam, both *in vivo* and *in vitro*, to include elevation in pain thresholds when administered orally (See Abstract). Additionally, it is important to note that the claims of the instant invention suggest the same compound as the Ito et al reference. Further, whatever characteristics the drugs have in the references necessarily flows to the claimed invention. Therefore Ito, et al clearly anticipates the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/

Examiner, Art Unit 1614

/Raymond J Henley III/
Primary Examiner, Art Unit 1614